UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,310	12/12/2005	Bernd Weigle	689290-244	4640

27162 7590 07/20/2007

CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI,
STEWART & OLSTEIN
5 BECKER FARM ROAD
ROSELAND, NJ 07068

EXAMINER	
HALVORSON, MARK	
ART UNIT	**PAPER NUMBER**
1642	

MAIL DATE	DELIVERY MODE
07/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,310	WEIGLE ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence comparison*.

DETAILED ACTION

Claims 1-36 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, drawn to a process for identifying an anti-neoplastic agent.

Group 2, claim(s) 8, drawn to a process for identifying an anti-neoplastic agent *in vivo*.

Group 3, claim(s) 9 and 10, drawn to a process for determining the cancerous status of a cell.

Group 4, claim(s) 11, 12, 27 and 28 drawn to an isolated peptide comprising an amino acid an amino acid sequence homologous to the amino acid sequence of SEQ ID NO:4.

Group 5, claim(s) 13-23, drawn to an antibody that reacts with a polypeptide comprising the amino acid sequence of SEQ ID NO:4.

Group 6, claim(s) 24-26 and 29 drawn to a process for treating cancer comprising administering an antibody.

Group 7, claim(s) 30, 31, 34 and 35 drawn to a process for treating a cancerous condition comprising administering a polypeptide.

Group 8, claim(s) 32, 34, and 35 drawn to drawn to a process for treating a cancerous condition
comprising administering a agent that modulates the activity of a cancer-related gene.

Group 9, claim(s) 33, 34 and 35 drawn to a process for protecting an animal against cancer.

Group 10, claim(s) 36, drawn to a method for procuring test data with respect to the gene modulating activity of a compound.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding, special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c), 37 C.F.R. 1.475(d)

The invention listed as Groups 1-10 do not relate to a single inventive concept under PCT Rule 1.31 because, under PCT 13.2 they lack the same or corresponding special technical feature for the following reasons:

A technical feature of the invention is a polypeptide comprising the amino acid sequence of SEQ ID NO:4 amino acid.

Glucksmann (US Patent Application Publication 2003/0022334, filed Feb 4, 2002) describes an identical polypeptide comprising the amino acid sequence of SEQ ID NO:4. (see sequence comparison).

Thus, the polypeptide comprising the amino acid of SEQ ID 4 does not contain a single inventive concept and puts a serious search burden on the Examiner.

SPECIES ELECTION

This application contains claims directed to the following patentably distinct species of the claimed invention. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

(i). Group 5 is subject to election of at least one of the disclosed species.

Claim 18 is generic to a plurality of disclosed patentably distinct species of cytotoxic agents whereby the agents are selected from the group consisting of: (a)

calicheamicin, (b) a **maytansinoid**, (c) an **adozelesin**, (d) a **cytotoxic protein**, (e) a taxol, (f) a **taxotere**, (g) a **taxoid** and (h) **DC1.**

(i)(a). The species **calicheamicin** above is further subject to restriction because claim 19 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the type of ovarian cancer is selected from the group consisting of : **calicheamicin γ_1, N-acetyl gamma calicheamicin dimethyl hydrazide or calicheamicin θ_1.**

(i)(d). The species **cytotoxic protein** above is further subject to restriction because claim 21 is generic to a plurality of disclosed patentably distinct species of cytotoxic proteins whereby the protein is selected from the group consisting of : **ricin, abrin, gelonin, pseudomonas exotoxin and diphtheria toxin**.

The species are independent or distinct because they are structurally different molecules.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at (571) 272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
Patent Examiner
571-272-6539

/Misook Yu/
Primary Examiner, Art Unit 1642

<!--StartFragment-->RESULT 1
US-10-067-668-2
; Sequence 2, Application US/10067668
; Publication No. US20030022334A1
; GENERAL INFORMATION:
; APPLICANT: Glucksmann, Maria Alexandra
; TITLE OF INVENTION: 33312, 33303, 32579, NOVEL HUMAN
; TITLE OF INVENTION: CYTOCHROME P450 FAMILY MEMBERS AND USES THEREOF
; FILE REFERENCE: 10448-136001
; CURRENT APPLICATION NUMBER: US/10/067,668
; CURRENT FILING DATE: 2002-02-04
; PRIOR APPLICATION NUMBER: 60/266,140
; PRIOR FILING DATE: 2001-02-02
; NUMBER OF SEQ ID NOS: 12
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 2
; LENGTH: 505
; TYPE: PRT
; ORGANISM: Homo sapiens
US-10-067-668-2

Query Match 100.0%; Score 2693; DB 4; Length 505;
Best Local Similarity 100.0%; Pred. No. 5.3e-222;
Matches 505; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

```
Qy          1 MEPSWLQELMAHPFLLLILLCMSLLLFQVIRLYQRRRWMIRALHLFPAPPAHWFYGHKEF 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MEPSWLQELMAHPFLLLILLCMSLLLFQVIRLYQRRRWMIRALHLFPAPPAHWFYGHKEF 60

Qy         61 YPVKEFEVYHKLMEKYPCAVPLWVGPFTMFFSVHDPDYAKILLKRQDPKSAVSHKILESW 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 YPVKEFEVYHKLMEKYPCAVPLWVGPFTMFFSVHDPDYAKILLKRQDPKSAVSHKILESW 120

Qy        121 VGRGLVTLDGSKWKKHRQIVKPGFNISILKIFITMMSESVRMMLNKWEEHIAQNSRLELF 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 VGRGLVTLDGSKWKKHRQIVKPGFNISILKIFITMMSESVRMMLNKWEEHIAQNSRLELF 180

Qy        181 QHVSLMTLDSIMKCAFSHQGSIQLDSTLDSYLKAVFNLSKISNQRMNNFLHHNDLVFKFS 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 QHVSLMTLDSIMKCAFSHQGSIQLDSTLDSYLKAVFNLSKISNQRMNNFLHHNDLVFKFS 240

Qy        241 SQGQIFSKFNQELHQFTEKVIQDRKESLKDKLKQDTTQKRRWDFLDILLSAKSENTKDFS 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 SQGQIFSKFNQELHQFTEKVIQDRKESLKDKLKQDTTQKRRWDFLDILLSAKSENTKDFS 300

Qy        301 EADLQAEVKTFMFAGHDTTSSAISWILYCLAKYPEHQQRCRDEIRELLGDGSSITWEHLS 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 EADLQAEVKTFMFAGHDTTSSAISWILYCLAKYPEHQQRCRDEIRELLGDGSSITWEHLS 360

Qy        361 QMPYTTMCIKECLRLYAPVVNISRLLDKPITFPDGRSLPAGITVFINIWALHHNPYFWED 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 QMPYTTMCIKECLRLYAPVVNISRLLDKPITFPDGRSLPAGITVFINIWALHHNPYFWED 420

Qy        421 PQVFNPLRFSRENSEKIHPYAFIPFSAGLRNCIGQHFAIIECKVAVALTLLRFKLAPDHS 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 PQVFNPLRFSRENSEKIHPYAFIPFSAGLRNCIGQHFAIIECKVAVALTLLRFKLAPDHS 480

Qy        481 RPPQPVRQVVLKSKNGIHVFAKKVC 505
              |||||||||||||||||||||||||
Db        481 RPPQPVRQVVLKSKNGIHVFAKKVC 505
```

<!--EndFragment-->